

TACROZ™ OINTMENT

Tacrolimus Ointment 0.1% w/w

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What Tacroz is used for

Tacroz is used to treat moderate to severe atopic dermatitis (eczema) in adults who are not adequately responsive to or are intolerant of conventional therapies such as topical corticosteroids.

Only Tacrolimus 0.03% is used to treat children (2 years of age and older) who failed to respond adequately to conventional therapies such as topical corticosteroids.

Tacroz is also used to treat moderate to severe atopic dermatitis (eczema) for the prevention of flares and prolongation of flare-free intervals in patients experiencing a high frequency of disease exacerbations (i.e. occurring 4 or more times per year) who have had an initial response to maximum 6 weeks treatment of twice daily Tacroz ointment.

How Tacroz works

The active substance of Tacroz , tacrolimus monohydrate, is an immunomodulating agent.

In atopic dermatitis, an over-reaction of the skin's immune system causes skin inflammation (itchiness, redness, dryness). Tacroz alters the abnormal immune response and relieves the skin inflammation and the itch.

Before you use Tacroz

- When you must not use it

If you are allergic to tacrolimus or any of the other ingredients of this medicine or to macrolide antibiotics (e.g. azithromycin, clarithromycin, erythromycin).

- Before you start to use it

Talk to your doctor

- If you have liver failure.
- If you have any skin malignancies (tumours) or if you have a weakened immune system (immuno-compromised) whatever the cause.
- If you have an inherited skin barrier disease such as Netherton's syndrome, lamellar ichthyosis (extensive scaling of the skin due to a thickening of the outer layer of the skin), or if you suffer from generalised erythroderma (inflammatory reddening and scaling of the entire skin).
- If you have a cutaneous Graft Versus Host Disease (an immune reaction of the skin which is a common complication after undergoing a bone marrow transplant).

•If you have swollen lymph nodes at initiation of treatment. If your lymph nodes become swollen during treatment with Tacroz , consult your doctor.

•If you have infected lesions. Do not apply the ointment to infected lesions.

•If you notice any change to the appearance of your skin, please inform your physician.

•Avoid exposing the skin to long periods of sunlight or artificial sunlight such as tanning beds. If you spend time outdoors after applying Tacroz , use a sunscreen and wear loose fitting clothing that protects the skin from the sun. In addition, ask your doctor for advice on other appropriate sun protection methods. If you are prescribed light therapy, inform your doctor that you are using Tacroz as it is not recommended to use Tacroz and light therapy at the same time.

Children

•Tacroz ointment is not approved for children younger than 2 years of age. Therefore it should not be used in this age group. Please consult your doctor.

•Tacroz 0.1 % ointment is not approved for children younger than 16 years of age. Therefore it should not be used in this age group. Please consult your doctor.

•The effect of treatment with Tacroz on the developing immune system in children, especially the young, has not been established.

Pregnancy and breast-feeding

If you are pregnant or breast-feeding, think you may be pregnant or are planning to have a baby, ask your doctor or pharmacist for advice before taking this medicine.

- Taking other medicines

Tell your doctor or pharmacist if you are using, have recently used or might use any other medicines especially:

- erythromycin (antibiotic)
- itraconazole, ketoconazole (antifungal)
- diltiazem (used to treat high blood pressure or heart problems).

You may use moisturising creams and lotions during treatment with Tacroz but these products should not be used within two hours of applying Tacroz .

The use of Tacroz at the same time as other preparations to be used on the skin or while taking oral corticosteroids (e.g. cortisone) or medicines which affect the immune system has not been studied.

How to use Tacroz

- How much to use

- Apply Tacroz as a thin layer to affected areas of your skin.
- Tacroz may be used on most parts of the body, including the face and neck and in the creases of your elbows and knees.
- Avoid using the ointment inside your nose or mouth or in your eyes. If the ointment gets on any of these areas, it should be thoroughly wiped off and/or rinsed off with water.
- Do not cover the skin being treated with bandages or wraps.

•Wash your hands after applying Tacroz unless your hands are also being treated.

•After a bath or shower, be sure your skin is completely dry before applying Tacroz .

- When to use it

Always use this medicine exactly as your doctor has told you. Check with your doctor or pharmacist if you are not sure.

- How long to use it

Children (2 years of age and older)

Apply Tacrolimus 0.03% ointment twice a day for up to three weeks, once in the morning and once in the evening. Afterwards the ointment should be used once a day on each affected region of the skin until the eczema has gone away.

Adults (16 years of age and older)

Two strengths of Tacrolimus Ointment (0.03% and 0.1%) are available for adult (16 years of age and older).

Your doctor will decide which strength is best for you.

Usually, treatment is started with Tacroz 0.1% ointment twice a day, once in the morning and once in the evening, until the eczema has cleared. Depending on the response of your eczema your doctor will decide if the frequency of application can be reduced or the lower strength, Tacrolimus 0.03% ointment, can be used.

TACROZ treatment should begin at the first appearance of signs and symptoms. Treat each affected region of your skin until the eczema has gone away.

Improvement is usually seen within one week. If you do not see any improvement after two weeks, see your doctor about other possible treatments.

- If you forget to use it

If you forget to apply the ointment at the scheduled time, do it as soon as you remember and then continue as before.

- If you use too much (overdose)

Contact your doctor immediately or go to the Emergency Department of your nearest hospital, if you think you or anyone else may have taken too much of this medicine. Do this even if there are no signs of discomfort or poisoning. You may need urgent medical attention.

While you are using it

- Things you must do

If you accidentally swallow the ointment, consult your doctor or pharmacist as soon as possible. Do not try to induce vomiting.

If you have any further questions on the use of this medicine, ask your doctor or pharmacist.

- Things you must not do

This medicines has been prescribed for you only. Do not pass it on to others. It may harm them, even if their signs of illness are the same as yours.

- Things to be careful of

Tacroz with alcohol

While using Tacroz , drinking alcohol may cause the skin or face to become flushed or red and feel hot.

Side effects

Like all medicines, this medicine can cause side effects, although not everybody gets them.

Very common:

- burning sensation and itching

These symptoms are usually mild to moderate and generally go away within one week of using Tacroz .

Common:

- redness
- feeling of warmth
- pain
- increased skin sensitivity
- skin tingling
- rash
- local skin infection including but not limited to: inflamed or infected hair follicles, cold sores, generalised herpes simplex infections
- facial flushing or skin irritation after drinking alcohol is also common

Uncommon :

- acne

Rosacea (facial redness), lentigo (presence of flat brown spots on the skin), swelling at the application site and herpes virus eye infections have been reported during post-marketing experience.

Since commercial availability a very small number of people who have used Tacroz ointment have had malignancies (for example lymphoma, including skin lymphoma, and other skin tumours). However, a link to Tacroz ointment treatment has not been

confirmed or refuted on the available evidence so far.

You may report any side effects or adverse drug reactions directly to the National Centre for Adverse Drug Reaction Monitoring by visiting the website npra.gov.my [*Consumers → Reporting Side Effects to Medicines (ConSERF) or Vaccines (AEFI)*]

Storage and Disposal of Tacroz Ointment

-Storage

Store below 25°C. Do not freeze.

-Disposal

Do not throw away any medicines via wastewater or household waste. Ask your pharmacist how to throw away medicines you no longer use. These measures will help to protect the environment.

Product Description:

-What it looks like

White to slightly yellowish ointment

-Ingredient(s)

-Active Ingredient:

Tacrolimus

-Inactive ingredients

- Mineral Oil
- Paraffin
- Propylene Carbonate
- White wax
- White Petrolatum

= MAL number:

Manufacturer

Glenmark Pharmaceuticals Ltd
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Pithampur, Dist. Dhar, (M.P) Pin
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Product Registration Holder

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